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10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2010 has been entered. Claims 10 and 12 have been amended. Claims 1-6, 8-10 and 12-21 are pending and under examination.

Objections Withdrawn

2. In view of Applicant's amendment, the objection to claims 10 and 12 for minor informalities is withdrawn.

Rejections Withdrawn

3. In view of Applicant's arguments, the rejection of claims 12-16 and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf; accessed on March 22, 2007), and further in view of What is Hyperkeratosis (Health A-Z- www.everydayhealth.com; accessed 5/19/10) and Seborrheic Keratosis (eMedicine Dermatology-www.emedicine.medscape.com; accessed 5/19/10) is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1-6, 8-10, 17 and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (This is a new matter rejection) is maintained for the reasons set forth in the previous office action on page 3, paragraph 5.

Applicant argues that:

1) Paragraphs 26-39 of the specification as filed describe intramuscular injections of botulinum toxin. Statements including "[T]o reconstitute vacuum-dried BOTOX.RTM., sterile normal saline without a preservative; (0.9% Sodium Chloride Injection) is used by drawing up the proper amount of diluent in the appropriate size syringe" (paragraph 26), "about 75-125 units of BOTOX.RTM. per intramuscular injection" (paragraph 28), "about 30-80 units of BOTOX.RTM. to treat constipation by intrasphincter injection of the puborectalis muscle" (paragraph 30), and "to treat strabismus, extraocular muscles have been injected intramuscularly with between about 1-5 units of BOTOX.RTM" (paragraph 32) all clearly imply the use of hollow bore needles to one of ordinary skilled

in the relevant art, as hollow bore needles have been used for years to deliver intramuscular injections.

2) The use of hollow bore needles is implicit.

Applicant's arguments have been fully considered and are deemed non-persuasive.

With regard to Points 1 and 2, contrary to Applicant's assertion, claim 1 as previously presented does not have implicit support. Applicant points to paragraphs 26-39 of the specification to implicitly meet the limitation of "hollow bore". However, it is the Examiner's position that while a vast majority of needles used in the industry are hollow bore, all needles that have the capacity to draw up a proper amount of diluent in an appropriate size syringe and/or the capacity to deliver an intramuscular injection does not necessarily mean that the needle has to be a hollow bore needle. Applicant does not point out specific basis for this limitation in the application, and none is apparent. To overcome this rejection Applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

As previously presented, Applicant has amended claim 1 to recite "…with a hollow bore" and "….wherein the administration of said liquid solution comprising botulinum toxin does not follow the administration of a first drug within said session". These phrases do not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Applicant points to the specification as filed for support for said amendment; however, the specification does not disclose anything regarding said amendments.

To overcome this rejection Applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

New Grounds of Objection and Rejection

Claim Objections

5. Claim 18 is objected to because of the following informalities: in the second sentence "dues" should be "due" to a hammertoe. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 8-10 and 12-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sanders (US 2006/0153876 A1; Filed: 2/24/03) in light of American College of Foot and Ankle Surgeons: Hammertoes.

Independent claim 1 is drawn to a method for treating skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection with a hollow bore needle per session; wherein the skin disorder comprises a wart, a callus, a swelling or scarring of a nerve that connects two toes, or a bunion; wherein the

botulinum toxin administered is less than the amount used to paralyze a muscle; and wherein the administration of said liquid solution comprising botulinum toxin does not follow the administration of a first drug within said session.

Independent claim 12 is drawn to a method for treating skin disorder in a patient in need thereof, the method comprising a step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder, wherein the solution is administered by intradermal injection or subdermal injection with a needle per session; wherein the skin disorder comprises a typical mole, a dysplastic mole, a pyogenic granuloma or a seborrheic keratose; and, wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

Sanders discloses methods and formulations that are useful for treatment and/or prevention of disease in mammals such as pain, inflammation, hyperpigmentation (seborrheic keratose), calluses and corns (see paragraphs 0133 and 0136). Sanders discloses a method of administering regulated SNARE inhibitors by local administration or administration methods well known in the art such as intramuscular, intradermal, parenteral and subcutaneous injections (see paragraph 0118). Sanders et al. disclose that the regulated SNARE inhibitors are readily commercially available and are, for example, botulinum toxin serotypes A, B, C1, D, E, F, G; available under Botox™ (serotype A) and Myocloc™ (see paragraphs 0067-68). Sanders discloses that for local injection, the compounds of the invention can be formulated in physiologically

compatible aqueous solutions, such as Hank's solution, or physiological saline buffer (see paragraph 0125). Moreover, Sanders discloses that the method of the present invention is useful for the treatment, reduction of symptoms and/or prevention of pain or inflammation (see paragraph 0137). Lastly, Sanders discloses that dosages and therapeutically effective amounts of botulinum toxin range from 0.001 units to about 10,000 units (see paragraph 0132).

With regard to claim 18, as evidenced by the American College of Foot and Ankle Surgeons (Hammertoes cited below under pertinent prior art) hammertoe symptoms, in addition to causing pain or irritation, include corns and calluses on the foot. Absent evidence to the contrary, the corns of Sanders developed due to a hammertoe because corns and calluses are commonly developed due to a patient having a hammertoe(s).

The instantly claimed method steps are identical to that of sanders. Absent evidence to the contrary, the intradermal or subdermal injection is with a hollow bore needle and is necessarily administered in amount that is less than the amount used to a paralyze a muscle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-6, 8-10 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders (US 2006/0153876 A1; Filed: 2/24/03), and further in view of Gibbs et al. (BJM, 2002; 325: 1-8).

Independent claim 1 is drawn to a method for treating skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection with a hollow bore needle per session; wherein the skin disorder comprises a wart, a callus, a swelling or scarring of a nerve that connects two toes, or a bunion; wherein the botulinum toxin administered is less than the amount used to paralyze a muscle; and wherein the administration of said liquid solution comprising botulinum toxin does not follow the administration of a first drug within said session.

Independent claim 12 is drawn to a method for treating skin disorder in a patient in need thereof, the method comprising a step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder, wherein the solution is administered by intradermal injection or subdermal injection with a needle per session; wherein the skin disorder comprises a typical mole, a dysplastic mole, a

pyogenic granuloma or a seborrheic keratose; and, wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

Dependent claim 6 is drawn to the method of claim 1, wherein the wart is a common wart, a plantar wart or a flat wart.

Sanders discloses methods and formulations that are useful for treatment and/or prevention of disease in mammals such as pain, inflammation, hyperpigmentation (seborrheic keratose), calluses and corns (see paragraphs 0133 and 0136). Sanders discloses a method of administering regulated SNARE inhibitors by local administration or administration methods well known in the art such as intramuscular, intradermal, parenteral and subcutaneous injections (see paragraph 0118). Sanders et al. disclose that the regulated SNARE inhibitors are readily commercially available and are, for example, botulinum toxin serotypes A, B, C1, D, E, F, G; available under Botox™ (serotype A) and Myocloc™ (see paragraphs 0067-68). Sanders discloses that for local injection, the compounds of the invention can be formulated in physiologically compatible aqueous solutions, such as Hank's solution, or physiological saline buffer (see paragraph 0125). Moreover, Sanders discloses that the method of the present invention is useful for the treatment, reduction of symptoms and/or prevention of pain or inflammation (see paragraph 0137). Lastly, Sanders discloses that dosages and therapeutically effective amounts of botulinum toxin range from 0.001 units to about 10,000 units (see paragraph 0132).

Sanders does not specifically disclose that the skin disorder comprises a wart, which is a common wart, a plantar wart or a flat wart as recited in claim 6.

Gibbs et al. disclose that cutaneous warts can be painful on the soles of the feet and near the nails and suggest that local treatments be used to treat said warts (see page 1, abstract and introduction).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sanders with the teaching of Gibbs et al. to treat, via the reduction of at least one symptom (i.e. pain) of said wart with botulinum toxin because a symptom of warts include pain and inflammation and botulinum toxin is a known agent for treating pain. Moreover, botulinum toxin has unique properties that make them beneficial in medical applications. Said properties are due to the botulinum toxins natural or wild-type form; their ability to block neuromuscular transmission for extended periods; the ability to, in most clinical applications, be used at doses that are below the level of immunological recognition; and lastly because they are remarkably safe for human use when injected into local areas due to the fact that there is little systemic spread of the toxin (see Sanders, paragraph 0009).

One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for a method of treating skin disorders in a patient in need thereof.

Since the claimed method steps were known in the prior art and one skilled in the art could have combined the steps as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. See the recent Board decision

Ex parte Smith,--USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Pertinent Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hammertoe (no date) American College of Foot and Ankle Surgeons, 2 pages;

Stulberg et al., Am Fam Physician, 2003; 68: 1955-60;

Stulberg et al., Am Fam Physician, 2003; 68: 1963-80.

9. No claim is allowed.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Patricia Duffy can be reached on 571-272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
12/30/10

/Vanessa L. Ford/

Primary Examiner, Art Unit 1645